

2025 Pre-Rulemaking Measure Review Preliminary Assessment

MUC ID	Title
MUC2025-034	Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management
Measure Steward & Developer	Proposed CMS Programs
American Heart Association (AHA)	Merit-based Incentive Payment System (MIPS) Link: Merit-based Incentive Payment System

Measure Overview
Rationale (excerpt from submission): Elevated low density lipoprotein cholesterol (LDL-C) levels contribute to clinical atherosclerotic cardiovascular disease (ASCVD) and once identified can be addressed via lipid management. Studies support that LDL-C lowering produces marked reduction in clinical ASCVD and that lower is better for LDL-C. There are currently no similar existing measures in use in CMS programs, as previous lipid monitoring measures were identified as topped-out with recent quality measurement focusing on statin therapy and management. Following the retirement of national lipid monitoring measures, a gap in care was identified using both AHA registry data and US Veterans data. In 2022, the AHA implemented two measures addressing lipid monitoring and management in their Get With The Guidelines – Outpace™ registry (Outpace), which supports a continued gap for both lipid monitoring and management. Measurement was beneficial to address the existing gap in lipid monitoring for patients with ASCVD and LDL-C management.
CMS-provided program rationale: CMS is considering adding this measure to the MIPS quality measure set as a new clinical quality measure. This outcome measure promotes care for adult patients with clinical atherosclerotic cardiovascular disease, ensuring patients diagnosed with this condition are tested for LDL-C and achieve an outcome of less than 70mg/dL. MIPS does not have any related measures that examine this outcome. This measure aligns with the CMS Meaningful Measures 2.0 framework and fits into priorities around chronic conditions. This measure has the potential to be in the primary care MIPS Value Pathway (MVP).
Description: Percentage of patients aged 18 years and older with clinical atherosclerotic cardiovascular disease (ASCVD) who received a low-density lipoprotein cholesterol (LDL-C) test via lipid panel and achieved an LDL-C of <70mg/dL on the most recent test during the measurement period.
Measure background: New measure never reviewed by the Measure Applications Partnership (MAP) Workgroup or PRMR; never used in a Medicare program.
Numerator: 1) Patients aged 18 years and older with clinical Atherosclerotic Cardiovascular (ASCVD) who had a low density lipoprotein cholesterol (LDL-C) tested via a lipid panel. 2) Patients aged 18 years and older with clinical ASCVD and had a lipid panel completed during the 12-month measurement period who achieved an LDL-C of <70 mg/dL on the most recent test during the 12-month measurement period.
Exclusions: N/A

Measure Overview	
Denominator: 1) All patients aged 18 years and older diagnosed with clinical Atherosclerotic Cardiovascular (ASCVD); 2) All patients aged 18 years and older with clinical ASCVD who had a low density lipoprotein cholesterol (LDL-C) tested via a lipid panel during the measurement period. Exclusions: Pregnancy; ESRD¹; hospice; over age 66+ with advanced illness, frailty, or dementia medications. Exceptions: Documentation of patient refusal of a lipid panel test during the 12-month measurement period: Medical Reason: Documentation of medical reason(s) for not managing lipid levels (i.e., history of drug-to-drug interactions, drug intolerance or allergy to both statin and PCSK9 lipid lowering therapies, patient planning to become pregnant). Patient Reason: Documentation of patient reason(s) for not managing lipid levels (i.e., patient unable to afford medications, patient refusal or non-compliance).	
Substantive changes from prior version (if applicable): N/A	
Measure type: Outcome	Measure is a composite: No Measure has multiple scores: Yes Measure is digital and/or an eQCM: No Measure is a paired or group measure: No
Level of analysis: Clinician: Individual and Group	Data source(s): - Digital-Administrative systems: Administrative Data (non-claims) - Digital-Clinical Registries; Digital-Electronic Health Record (EHR) Data - Digital-Laboratory Systems Data
Care setting(s): Ambulatory/office-based care	Risk adjustment or stratification: No
CBE endorsement status: Not Endorsed	CBE endorsement history: Never submitted
Is measure currently used in CMS programs? No	Measure addresses statutorily required area? No

¹ End-stage renal disease

Evaluation

Meaningfulness

Importance	
Type of evidence:	Peer-Reviewed Original Research [MUC Entry/Review Information Tool (MERIT) Submission Form]
Importance: As referenced in the literature review provided by the developer, there is a need for measures focusing on LDL-C monitoring. There are currently no similar existing measures in use in CMS programs, as previous lipid monitoring measures were identified as topped-out with recent quality measurement focusing on statin therapy and management. The developer cites evidence from peer-reviewed studies showing that this new measure could provide an opportunity to address disparities in care, as women have a lower likelihood of attaining LDL-C goals than men. The evidence also identified differences in treatment and outcomes based on race and sex. The measure aligns with CMS health priorities and patient goals to achieve an LDL-C of <70mg/dL. Further, the National Lipid Association has strongly advocated for the measurement and monitoring of lipids to address public health needs. Patient feedback during development strongly supported the use of the measure to drive improvement.	
Rating: Met	

Conformance	
Measure alignment with conceptual intent: This measure intends to estimate the percentage of patients diagnosed with ASCVD who undergo an LDL-C test via lipid panel and achieve an LDL-C of <70mg/dL on the most recent test. The measure numerator, denominator, and exclusions for the measure scores are defined and support the intent of the measure. This measure is reported as two performance rates: 1) percentage of patients aged 18 years and older with clinical ASCVD who received an LDL-C test via lipid panel and 2) percentage of patients who received an LDL-C test via lipid panel and achieved an LDL-C of <70mg/dL on the most recent test during the measurement period. The measure aligns with MIPS objectives to 1) improve beneficiary health through prevention, as heart disease remains the leading cause of mortality in the United States; 2) educate, engage, and empower patients as members of their care team; and 3) provide accurate, timely, and actionable performance data to clinicians, patients, and other stakeholders.	
Rating: Met	

Feasibility	
eCQM feasibility testing/analysis conducted:	No, not an eCQM
Feasibility: Data elements for this measure are routinely collected in EHRs, claims data, clinical registries, and digital lab systems data. The	

Feasibility

measure can be implemented without significant workflow changes. The submission materials did not identify any major technical barriers associated with this measure.

Considerations for the committee: Committee members should reflect on professional and patient experiences and consider additional feasibility challenges and facilitators for this measure within the MIPS measured entity population across facilities, including rural settings.

Rating: Met

Validity

Validity testing method(s):	Empiric and Face Validity [MERIT Submission Form]
Testing level(s)	Clinician - Individual
Was this measure tested in the same target population as MIPS?	Yes

Validity: The developer established the face validity of this measure by asking members of the technical expert panel (TEP) if the measure—including both score 1 and 2 as outlined in the specification—was meaningful. Out of the 24 members, 19 agreed that the measure was meaningful and addressed an important clinical gap. The submission form did not provide information on any concerns voiced by the five members who did not agree that the measure was meaningful.

For the monitoring measure rate (score 1), the developer conducted empiric validity testing among a sample of 243 clinicians by analyzing the correlation of performance scores between the new monitoring measure rate and MIPS measure Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan. When correlating each clinician's measure performance, the developer found a correlation coefficient (r) of 0.577. The results indicate a moderate positive correlation between the two measures, demonstrating the empiric validity of the new monitoring measure rate as a meaningful assessment of quality of care.

For the management measure rate (score 2), the developer conducted empiric validity testing among a sample of 155 clinicians by analyzing the correlation of performance scores between the new management measure rate and MIPS measure Hemoglobin A1c (HbA1c) Poor Control (>9%). When correlating each clinician's measure performance, the developer found a correlation coefficient (r) of 0.568. The results indicate a moderate positive correlation between the two measures, demonstrating the empiric validity of the new management measure rate as a meaningful assessment of quality of care.

This measure is submitted for use at the individual and group clinician level but lacks validation at the clinician-group level based on submission materials. The developer may wish to expand testing of this measure to improve the scientific acceptability of this measure for use in MIPS.

Threats to validity: The measure is not risk adjusted, nor is it recommended for stratification; however, the lack of risk adjustment is addressed through denominator exclusions such as pregnancy; end-stage renal disease (ESRD); hospice; patients over the age of 66 with advanced illness, with frailty, or who are on dementia medications.

Considerations for the committee: Based on professional and patient experiences, committee members should reflect on if the face validity

Validity

and moderate correlations demonstrated during empiric validity testing are sufficient evidence that this measure has the required scientific rigor for inclusion in a pay-for-performance program. Are the selected comparison measures appropriate for validating each measure score? Are any threats to validity not accounted for through exclusion that would impact payment to participating clinicians?

Rating: Not Met but Addressable

Reliability**Reliability testing method(s):**

Signal-to-noise [MERIT Submission Form]

Testing level:

Individual Clinician

Reliability discussion: The developer conducted reliability testing at the national provider identifier (NPI) level across four health systems using data gathered between January 1, 2024, and December 31, 2024, selected to maximize sample diversity and data completeness given available data and sampling constraints.

In the LDL-C monitoring group (measure score 1), 286 NPIs were evaluated with a mean reliability score of 0.833; 87.1% had scores above the 0.6 threshold, indicating strong performance differentiation. In the LDL-C management group (measure score 2), 215 NPIs were assessed with a mean reliability of 0.759, and 72.1% exceeded the 0.6 threshold, supporting the measure's ability to reflect true variation across individual clinicians.

In response to an inquiry about availability of group-level reliability testing during evaluation for this PA, the developer shared that formal comparison of reliability between health systems is not feasible at this time due to the small number of systems during testing, which limits statistical power and precision. The developer noted that NPI-level reliability provides a conservative estimate, as aggregation typically reduces random variation and increases reliability, supporting the measure's scientific acceptability for both individual and group clinician use. For this evaluation, this measure may be considered "met" for individual clinician level while further examination of group-level reliability is needed.

Considerations for the committee: As the measure submission indicates that this measure is specified for use at the individual and group clinician level, committee members should consider if individual clinician-level reliability testing only provides a sufficient level of scientific acceptability.

Additional reliability analyses: No additional analyses were conducted.

Rating: Not Met but Addressable

Usability**Usability considered in application:**

No, the submission materials do not discuss the measure's usability within MIPS.

Usability discussion: The developer did not include information on potential barriers or facilitators to use within MIPS. The developer noted

Usability

that during a public comment period, an individual raised a concern about how combining the concepts within one measure with two scores may result in masking variations in care delivery because LDL-C testing (score 1) and patient goal attainment (monitoring rate 2) reflect different processes and might be influenced by distinct factors. The developer added they will monitor whether requiring an annual assessment may lead to overuse of LDL testing.

During collaboration on this assessment, the developer noted that the prior Physician Quality Reporting System (PQRS) utilized similar concepts, demonstrating the usability of the measures in accountability programs. The American Heart Association's (AHA's) Outpace Registry adopted the measure concepts in 2022. Over the course of implementation, patient- and encounter-level testing conducted by engaged facilities and their users, AHA staff, and registry vendor has found the measure to be meaningful.

Additionally, the 2025 American College of Cardiology (ACC)/AHA Clinical Performance and Quality Measures for Patients with Chronic Coronary Disease (CCD) encourages the use of lipid measurement in patients with CCD as an accountability or performance metric. In 2023, Ballantyne, et al. encouraged the re-establishment of LDL-C measurement and control as a quality metric for the U.S. health care system. These examples demonstrate the measure's usability in different contexts.

Considerations for the committee: Based on professional and patient experiences, committee members should reflect on potential barriers or facilitators to use of this measure among MIPS clinicians.

Rating: Met

Appropriateness of Scale

Appropriateness of Scale

Similar or related measures in program(s):	None identified
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Measure balance, burden, and value across target populations/measured entities: The measure developer did not provide information on the balance, potential burden, or value it could bring to the target patient populations or MIPS-participating clinicians.

Considerations for the committee:

- How might different populations see different benefits or burdens from use?
- Will the measure have the same impact in rural or low-resource settings?
- Is the measure more appropriate for some care settings versus others within MIPS?

Time-to-Value Realization

Time-to-Value Realization	
Plan for near- and long-term impacts after implementation:	None specified
Measure implementation impacts over time: While the developer briefly mentions potential outcomes for measuring and monitoring LDL-C on specific patient populations in the literature review, there is a need for further examination of near- and long-term impacts of this measure after implementation across clinician and patient populations. Considerations for the committee: • What are the potential near- and long-term impacts of this measure on measured entities, proposed CMS program, and patient populations? • Will benefits and burdens associated with this measure be realized within an appropriate implementation time frame? • How will this measure mature through revisions in the future if added to the MIPS measure set?	